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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/567,064

08/23/2006

Niza Frenkel

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20529 7590 08/04/2010  
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EXAMINER

MONTANARI, DAVID A

ART UNIT

PAPER NUMBER

1632

MAIL DATE

DELIVERY MODE

08/04/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/567,064	FRENKEL, NIZA	
	<b>Examiner</b>	<b>Art Unit</b>	
	David Montanari	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 72, 73 and 76-91 is/are pending in the application.
- 4a) Of the above claim(s) 89-91 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 72, 73 and 76-88 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicants arguments and amendments filed on 5/13/2010 have been entered (the response below is to Applicants arguments filed on 4/28/2010).
2. Claims 72, 80 and 88 are amended.
3. Claims 74 and 75 have been cancelled.
4. The rejection of claims 72, 73, 78 and 81 under Double Patenting over U.S. Patent No. 6,503,752 is withdrawn in view of Applicant's amendments to the claims.
5. The rejection of claims 72, 73 and 76-88 under 35 USC 112, 1st parag. written desc. is withdrawn in view of Applicant amending claim 72 to recite that the sequences are amplicon-6 and Tamplicon-7.
6. The rejection of claims 72 and 88 under 35 USC 112, 2nd parag. is withdrawn in view of Applicant's amendments to the claims.
7. The rejection of claims 72, 73 and 76-88 under 35 USC 102(e) is withdrawn in view of Applicant's arguments that Applicant is the sole inventor of the instant application and the sole inventor of U.S. Patent No. 6,503,752, and thus cannot be applied under the 102(e) statute.
8. Claims 72, 73 and 76-88 are examined in the instant application.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 72, 73 and 76-88 are rejected under 35 U.S.C. 102(b) as being anticipated by Frenkel N. (PCT/US94/12715, published 18-May 1995).

Regarding claim 72, Frenkel teaches that the vector can comprise a Tamplicon sequence, which is a DNA sequence derived from HHV-6 or HHV-7 (pg. 9 lines 20-29) and that said vector comprises an origin of replication, cleavage and packaging signal and promoter, this is taught at pg. 7 lines 10-14. The Tamplicon-7 sequence of the pending claims is the same as the tamplicon sequence taught by Frenkel since both are derived from HHV-7 and further comprises the same pac sites (see Fig. 4 of Frenkel and Figs. 1 and 2 of the instant invention).

Regarding claim 73, Frenkel teaches that the claimed vector will form concatemers (pg. 4 lines 14-18).

Regarding claim 76, Frenkel teaches that the vector is packaged in a virion particle (pg. 20 lines 8-13).

Regarding claim 77, Frenkel teaches that HHV-6 expression leads to exanthem subitum, which is an immune response to HHV-6 protein expression (pg. 3 lines 32-34).

Regarding claims 78 and 81, Frenkel teaches that the vector of the claimed invention can comprise a foreign nucleic acid sequence such as a detectable marker (pg. 13 lines 2-5).

Regarding claims 79 and 80, Frenkel teaches that the foreign nucleic acid sequence can be targeted to the cell membrane (pg. 14 lines 3-14) or secreted out of the cell (pg. 14 lines 15-21) where the production of insulin or enzymes are used to treat diseases associated with their deficiencies.

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Regarding claim 82, Frenkel teaches that their claimed vector is "useful as an agent for genetic therapy in the treatment of various malignancies, viral infections, enzyme deficiencies and others, of lymphatic cells as well as other cells capable of being infected with HHV-6 or HHV-7" (pg. 9 lines 15-18).

Regarding claims 83, 84 and 88, Frenkel teaches that a helper virus will be provided along with the claim vector to assist in the replication of the Tamplicon (pg. 9 lines 22-24) and that a cell will comprise the helper virus (pg. 23 lines 19-21).

Regarding claims 85, 86 and 87, Frenkel teaches that the vector of the invention may also be used for infection of lymphocytes ex vivo and then returned to a patient (pg. 16 lines 3-4), wherein the vector comprises a foreign nucleic acid sequence (pg. 7 lines 15-22). Further it is art accepted that lymphocytes comprise B and T cells and thus the lymphocytes infected by the vector taught by Frenkel would encompass the B and T cells of claim 87.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is (571)272-3108.

The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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AU 1632

/Peter Paras, Jr./  
Supervisory Patent Examiner, Art Unit 1632